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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,471	02/27/2007	Tatsuya Konishi	KPO-TSC-P3/TK-93/US	3141

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EXAMINER	
KASSA, TIGABU	

ART UNIT	PAPER NUMBER
1619	

NOTIFICATION DATE	DELIVERY MODE
05/27/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/560,471	KONISHI ET AL.	
	Examiner	Art Unit	
	TIGABU KASSA	1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 May 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11,13 and 15-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11, 13,and 15-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to the amendment filed July 06, 2009. **Claims 11, 13, and 15-19 are pending. Claims 11, 13, and 15-19 are under examination in the instant office action**. Claims 1-10, 12, and 14 are cancelled. Claims 17-19 are newly added. Applicant's amendment has necessitated a new ground of rejection.

Request for continued examination

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 05/13/10 has been entered.

Moot Rejections/Objections

All rejections and/or objections of claims 1-10, 12, and 14 cited in the previous office action mailed on November 23, 2009 are moot, because said claim(s) has/have been cancelled.

New Rejections

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 15 is rejected under 35 U.S.C. § 102(b) as being anticipated by Yamasaki et al. (WO 01/47559) using for translation the equivalent Yamasaki et al. (US Patent No. 7018647) as evidenced by Patel et al. (US Patent No. 4855294).

Instant claim 15 recites a method of reducing irritation of the skin caused by a counter-irritant used in an analgesic and anti-inflammatory patch by using benzocaine as an active ingredient in the patch, wherein the patch further comprising poultice material containing 10 to 80 wt% water.

Yamasaki et al. disclose an external skin patch having improved **painkilling effect for pains accompanied by inflammation**, such as chronic arthrorheumatism, arthrosis deformans or low back pain (see abstract). Yamasaki et al. disclose that an external skin patch is obtained by coating a drug-containing base on a substrate; the drug-containing base comprises an adhesive gel base containing a water soluble polymeric material, a crosslinking agent, water and a humectant as essential components, and a local anesthetic and a nonsteroidal antiphlogistic analgesic agent as medicinal components (see abstract). Yamasaki et al. disclose **an external skin patch comprising a formulation of benzocaine (7% w/w), based on examiner's calculation 48.3 % of water, glycerin (counter-irritant) (10%) and other ingredients** (column 6, example 2, and lines 28-54). The examiner notes that Yamasaki et al. applies the composition externally to the skin for painkilling. Yamaski practices the exact same method step as instantly claimed using the same composition. Therefore, the method of Yamaski would necessarily and inherently reduce irritation of the skin.

Note: Patel et al. is incorporated in the rejection as an evidentiary reference in order to verify that glycerin is an anti-irritation agent (see abstract and claim 1).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically taught or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness

Claims 11, 13, and 16-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamasaki et al. (WO 01/47559) using for translation the equivalent Yamasaki et al.

(US Patent No. 7018647) in view of Hirashima et al. (US Patent No. 6471984) and as evidenced by Patel et al. (US Patent No. 4855294).

Applicant Claims

The claimed subject matters of instant claims 11, 13, and 16-19 are set forth above.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Yamasaki et al. are set forth above.

Ascertainment of the Difference between Scope the Prior Art and the Claims (MPEP §2141.012)

Yamasaki et al. do not explicitly teach the specific ingredients with counter-irritation effects listed in instant claims 11, 13, and 16-17. This deficiency is cured by the teachings of Hirashima et al..

Hirashima et al. teach a patch containing a plasticizer 3-L-menthoxypropane-1,2-diol, which is excellent in overall feeling such as adhesion and fit feeling to the skin and peeling pain (see abstract). Hirashima et al. also teach a cataplasm (poultice) and a tape-aid (plaster) each containing the plasticizer (column 1, lines 15-17). The drugs that can be used in the patch include benzocaine (column 3, line 8). **The content of the drug is preferably 0.1 to 20% by weight, more preferably 0.5 to 10% by weight, of the total amount of the base for the patch** (column 3, lines 25-27). The patch further contain various pharmacologically acceptable additives, such as a stabilizer, an antioxidant, a perfume, a filler, an ultraviolet absorber, an antiseptic, an antimicrobial agent and a percutaneous absorbefacient (column 3, lines 29-34). Hirashima et al. teach that as the base for the cataplasm, a hydrophilic base comprising a water-soluble polymer, a polyhydric alcohol and water is preferable in consideration of long-term stability, releasability

and percutaneous absorbability of drug, and safety for the skin (column 3, line 41-45). In the base the content of water is preferably **10 to 90% by weight, more preferably 20 to 80% by weight**, based on the total amount of the hydrophilic base. The water is necessary in order **to solubilize the water-soluble polymer to thereby make the resulting base develop its thickening, cohesive and shape-retaining properties**. The hydrophilic base of the cataplasm may contain one or more additives, for example, ultraviolet absorbers such **glycol salicylate, methyl salicylate and phenyl salicylate** (column 4, lines 49-50), which are ingredients with counter-irritation effect.

Note: Patel et al. is incorporated in the rejection as an evidentiary reference in order to verify that glycerin is an anti-irritation agent (see abstract and claim 1).

Finding of Prima Facie Obviousness Rationale and Motivation (MPEP §2142-2143)

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the teachings of Yamasaki et al. by incorporating the counter-irritation agent recited in instant claims 13 and 16 in the medical adhesive patch, because Hirashima et al. teaches that counter-irritants like **glycol salicylate, methyl salicylate and phenyl salicylate** can be included in a patch that may contain drugs like benzocaine to alleviate pain and skin irritation. An ordinary skilled artisan would have been motivated to substitute the counter-irritant glycerin with the other counter-irritants recited in instant claims 11, 13, and 16-17 because the anti-irritation agents are functionally equivalent and can equally perform the intended purpose. Furthermore, the ingredients with the counter irritation effect are conventionally known in the art. An ordinary skilled artisan would have had a reasonable

expectation of success upon combination of the Yamasaki et al. and Hirashima et al., because both references teach similar compositions delivered in a patch for alleviation of pain. The examiner notes that in the claim amendment applicants resorted to incorporating an intended use in instant claim 11. The examiner takes the position that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The examiner notes that indeed the prior art structure is capable of performing the intended use since structurally it is similar to the instantly claimed product. In the case where the claimed ranges for the amounts of the ingredients "overlap or lie inside ranges disclosed by the prior art" a *prima facie* case of obviousness exists. In re Wertheim, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); In re Woodruff, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). Similarly, a *prima facie* case of obviousness exists where the claimed ranges and prior art ranges do not overlap but are close enough that one skilled in the art would have expected them to have the same properties. Titanium Metals Corp. of America v. Banner, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985). Furthermore, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

In light of the forgoing discussion, one of ordinary skill in the art would have concluded that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Claims 11, 13, and 16-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamasaki et al. (WO 01/47559) using for translation the equivalent Yamasaki et al. (US Patent No. 7018647) and further in view of Bernstein (US Patent No. 4997853) and as evidenced by Patel et al. (US Patent No. 4855294).

Applicant Claims

Instant claim 11 recites the analgesic and anti-inflammatory patch according to claim 10, containing the ingredient having a counter-irritation effect in an amount of 0.01 to 30 wt % when it is one of l-menthol, dl-menthol, dl-camphor, d-camphor, methyl salicylate, glycol salicylate, mentha oil and eucalyptus oil, or in an amount of 0.001 to 5 wt % when it is one of capsaicin, one of capsicum extract and nonylic vanillylamide for the treatment of muscle pain, joint pain, lumbago, shoulder stiffness and fracture pain. Instant claim 13 recites an analgesic and anti-inflammatory patch comprising an aqueous poultice material containing 10 to 80 wt % water, 0.5 to 20 wt % of benzocaine, and at least one ingredient having a counter-irritation effect selected from the listed recited in the instant claim. Instant claim 11 recites the analgesic and anti-inflammatory patch according to claim 13, containing the ingredient having a counter-irritation

effect in an amount of 0.01 to 30 wt % when it is one of l-menthol, dl-menthol, dl-camphor, d-camphor, methyl salicylate, glycol salicylate, mentha oil and eucalyptus oil, or in an amount of 0.001 to 5 wt % when it is one of capsaicin, one of capsicum extract and nonylic vanillylamide. Instant claim 16 recites a method of reducing the pains of muscle pain, joint pain, lumbago, shoulder stiffness, and fracture pain without unpleasant irritation when topically applied, by applying an analgesic and anti-inflammatory patch comprising an aqueous poultice material containing 10 to 80 wt% water, 0.5 to 20 wt% of benzocaine, and at least one ingredient having a counter-irritation effect selected from the list. Instant claim 17 recites an analgesic and anti-inflammatory patch comprising an aqueous poultice material containing 10 to 80 wt% water, 0.5 to 20 wt% of benzocaine, and at least one ingredient having a counter-irritation effect selected from the list. Instant claim 18 recites the analgesic and anti-inflammatory patch according to claim 17, wherein the aqueous poultice material comprises 3 to 40 wt% of at least one water-soluble polymer, the water-soluble polymer being selected from the list. Instant claim 19 recites the analgesic and anti-inflammatory patch according to claim 18, wherein the aqueous poultice further comprises 0.001 to 5 wt% of at least one crosslinker to crosslink the water-soluble polymer, the crosslinker being selected from the list.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Yamasaki et al. teach an external skin patch having improved **painkilling effect for pains accompanied by inflammation**, such as chronic arthrorheumatism, arthrosis deformans or low back pain (see abstract). Yamasaki et al. disclose that an external skin patch is obtained by coating a drug-containing base on a substrate; the drug-containing base comprises an adhesive

gel base containing **a water soluble polymeric material, a crosslinking agent, water and a humectant as essential components, and a local anesthetic and a nonsteroidal antiphlogistic analgesic agent as medicinal components** (see abstract). Yamasaki et al. disclose **an external skin patch comprising a formulation of benzocaine (7% w/w), based on examiner's calculation 48.3 % of water, glycerin (counter-irritant) (10%) and other ingredients** (column 6, example 2, and lines 28-54). **Yamasaki et al. teach examples of water soluble polymeric substance include gelatin, starch, agar, mannan, alginic acid, polyacrylic acid, a salt of polyacrylic acid, dextrin, methyl cellulose, hydroxypropyl cellulose, methyl cellulose sodium, carboxymethyl cellulose, carboxymethyl cellulose sodium, polyvinyl alcohol, polyvinyl pyrolidone, methyl vinyl ether-maleic anhydride copolymer, gum Arabic, gum tragacanth, karaya gum, locust bean gum, and the like** (column 3, lines 34-40). The amount of the above-mentioned water soluble polymeric materials added to the adhesive gel base is **preferably 0.5-50% by weight, more preferably 5-25% by weight** (column 3, lines 46-49). **The content of the water soluble polymeric material falling within the above-mentioned range is preferable since the water retaining properties, adhesion and feel on use are improved** (column 3, lines 49-53). Yamasaki et al. teach that as the crosslinking agent, both organic and inorganic crosslinking agents can be employed, however, an aluminum compound is preferable (column 3, lines 54-56). **Examples of the aluminum compound include aluminum hydroxide, aluminum chloride, aluminum silicate hydrate, synthetic aluminum silicate, dry aluminum hydroxide gel, aluminum acetate, aluminum lactate, aluminum stearate, magnesium aluminometasilicate, dihydroxyaluminum aminoacetate** etc (column 3, lines 57-62). **These crosslinking agents can impart an appropriate strength to the gel as an initial**

property, prevent the strength of the gel from lowering, as they carry out efficient crosslinking with the polymeric material, maintain the form retaining properties, improve the stability of the properties of the preparations with time, and improve the workability and feel on use (column 3, lines 62-67 and column 4, line 1). The amount of the above-mentioned **crosslinking agents in the adhesive gel base is preferably 0.001-10% by weight, more preferably it is 0.01-5% by weight** (column 4, lines 3-5).

Note: Patel et al. is incorporated in the rejection as an evidentiary reference in order to verify that glycerin is an anti-irritation agent (see abstract and claim 1).

Ascertainment of the Difference between Scope the Prior Art and the Claims (MPEP §2141.012)

Yamasaki et al. do not explicitly teach the specific ingredients with counter-irritation effects listed in instant claim 11 and 16-17. Additionally, Yamasaki et al. do not explicitly teach the concentration ranges for the ingredient having a counter-irritation effect. These deficiencies are cured by the teachings of Bernstein for obviating from the Markush list of the counter-irritation agents reciting in the other alternative including capsaicin etc.

Bernstein teaches a method for treating superficial pain syndromes, said method comprising the step of topically applying to a patient having superficial pain, an effective amount of a composition comprising a therapeutically acceptable carrier and capsaicin, said **capsaicin being present in a concentration, by weight, from about 0.01% to about 1.0%**, said composition also including a topical anesthetic in a therapeutically effective amount, said anesthetic being present primarily to inhibit the local topical irritant effect of said capsaicin and

whereby said capsaicin provides the primary relief for the pain syndrome (see claim 1). The anesthetic can **be benzocaine** (see claim 3).

Finding of Prima Facie Obviousness Rationale and Motivation (MPEP §2142-2143)

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the teachings of Yamasaki et al. by incorporating the counter-irritation agent capsaicin in the medical adhesive patch composition containing an ingredient with a counter-irritation effect such as capsaicin in a concentration of 0.001 to 5 wt %, because Bernstein teaches the similar composition containing capsaicin in concentration of from about 0.01% to about 1.0% for the same intended purpose. An ordinary skilled artisan would have been motivated to incorporate the capsaicin in concentration of from about 0.01% to about 5.0% because at higher concentrations the capsaicin can cause burning and irritation. An ordinary skilled artisan would have had a reasonable expectation of success upon combining the teachings of Yamasaki et al. and Bernstein, because both references teach the similar compositions for the same intended purpose namely relief of pain. The examiner notes that in the claim amendment applicants resorted to incorporating an intended use in instant claim 11. The examiner takes the position that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The examiner notes that indeed the prior art structure is capable of performing the intended use since structurally it is similar to the instantly claimed product. In the case where the claimed ranges for the amounts of the ingredients "overlap or lie inside ranges disclosed by the prior art" a *prima facie* case of

obviousness exists. In re Wertheim, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); In re Woodruff, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). Similarly, a *prima facie* case of obviousness exists where the claimed ranges and prior art ranges do not overlap but are close enough that one skilled in the art would have expected them to have the same properties. Titanium Metals Corp. of America v. Banner, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985). Furthermore, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

In light of the forgoing discussion, one of ordinary skill in the art would have concluded that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Response to arguments

Applicant's arguments filed 05/13/10 have been fully considered but they are not persuasive. *Applicants argue that Bernstein fails to disclose a patch in the form of an aqueous poultice material containing 10 to 80wt% water. Moreover, Bernstein only discloses capsaicin; there is no mention or suggestion of l-menthol, dl-menthol, dl-camphor, d-camphor, methyl salicylate, glycol salicylate, mentha oil, eucalyptus oil, or and nonylic vanillylamide, nor the*

suggestion of using up to 5wt% of capsaicin. The largest amount of capsaicin suggested in Bernstein is 1 wt% (see claim 5 and columnl, line 42 of the Bernstein reference). In addition, the focus of the Bernstein reference is to use benzocaine to reduce burning and pain caused by use of capsaicin. There is nothing in Bernstein that would suggest the combination of benzocaine and counter-irritant for non-superficial pain, since Bernstein is directed to "superficial pain syndromes such as postherpetic neuralgia" (See column 1, lines 13-14). The examiner respectfully disagrees with applicants' assertions because the aqueous poultice material containing 10 to 80 wt% water and the incorporation of benzocaine and counter-irritant are clearly addressed by the teachings of Yamasaki et al. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Furthermore, the instantly claimed counter-irritation agents are recited in a Markush list of alternatives, therefore, all that is required is that the prior art meet a single alternative from the list.

Applicants also argue that the drugs to be used in the patch of Hirashima et al. are not the focus of the disclosure and are presented as a laundry list of anything that could possibly be used. There is no reason, other than hindsight using the present application, to select benzocaine out of this list. Even more telling, methyl salicylate and glycol salicylate are buried in a list of dozens of additives to the hydrophilic base of Hirashima and identified as ultraviolet absorbers, not as counter-irritants. No one skilled in the art would have any reason to combine these two random components of the Hirashima et al. patent except by using the present application as a

guide and impermissible hindsight to conduct a computer search to select these two items out of the hundreds listed in the Hirashima et al. reference. Moreover, Hirashima does not list the other counter-irritants claimed. Likewise, one would not combine the Hirashima and Yamasaki et al. references to obtain the patch and method of the present invention as claimed in claims 13 and 16. The examiner respectfully disagrees with applicants' assertions because the drug to be used which is benzocaine is clearly addressed by the teachings of Yamasaki et al. as set forth above. Furthermore, the mention of methyl salicylate and glycol salicylate as ultraviolet absorbers does not necessarily remove their inherent property as counter irritant. Hirashima indeed teach that the drug to be used in the patch is not particularly limited but may be arbitrarily selected from among known conventional drugs such as anti-inflammatory like **glycol salicylate and methyl salicylate (column 2, lines 54-55).** One of ordinary skill in the art would have been motivated to include glycol salicylate or methyl salicylate in the patch of Yamasaki because these anti-inflammatory agents are functionally equivalent with the anti-inflammatory agent glycerine in Yamaski. One of ordinary skill in the art would have been motivated to substitute one anti-inflammatory agent with the other because they are functionally equivalent and can perform the anti-inflammatory effect.

Addressing the issue of obviousness, the Supreme Court noted that the analysis under 35 USC 103 "need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." *KSR* at 1741. The Court emphasized that "[a] person of ordinary skill is… a person of ordinary creativity, not an automaton." *Id.* at 1742. Consistent with this reasoning, it would have been obvious to substitute one anti-inflammatory agent with

the other to perform the same function. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Applicants have not demonstrated how their product and method are patentably distinct from the cited prior arts nor do the claims as currently written distinguish the instant invention over the prior arts. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

Claims 11, 13, and 15-19 are rejected. Claims 1-10, 12, and 14 are cancelled. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIGABU KASSA whose telephone number is (571)270-5867. The examiner can normally be reached on 9 am-5 pm Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne P. Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Tigabu Kassa
/YVONNE L. EYLER/
Supervisory Patent Examiner, Art Unit 1619

05/20/10